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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/672,591	09/26/2003	William H. Eby	1421-136	8643
32905	7590	09/27/2005		
JONDLE & ASSOCIATES P.C. 858 HAPPY CANYON ROAD SUITE 230 CASTLE ROCK, CO 80108				

EXAMINER	
MCELWAIN, ELIZABETH F	

ART UNIT	PAPER NUMBER
1638	

DATE MAILED: 09/27/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/672,591

Applicant(s)

EBY ET AL.

Examiner

Elizabeth F. McElwain

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 9/26/03.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>4/15/05</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1-22 are pending.

Claims 1, 2, 7, 12, 14 and 16 are objected to for the inclusion of a blank line where the ATCC Accession number should be.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 2, 6, 7, 12, 14, 16-18 and 21 and claims 3-6, 8-11, 13, 15, 19 and 22 dependent thereon, are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1, 2, 7, 12, 14 and 16, and claims 3-6, 9-11, 13, 15, and 17-22 dependent thereon, are indefinite in the recitation of "a soybean seed designated S030150", given that a name does not clearly identify the claimed soybean cultivar and seed, and does not set forth the metes and bounds of the claimed invention. Since the name S030150 is not known in the art, the use of said name does not carry art recognized limitations as to the specific characteristics or essential characteristics which are associated with that denomination. In addition, the name appears to be arbitrary and the specific characteristics associated therewith could be modified, as there is no written description of the soybean plant that encompasses all of its traits. Amending the claims to recite the ATCC deposit number would overcome the rejection.

Claim 6 is indefinite in that "said cell or a protoplast of the tissue culture" lacks antecedent basis, since the claim on which it depends recites "cells" in plural, and there is no recitation of "protoplast" in claim 5.

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Claim 12 is indefinite in that it is drawn to producing a soybean variety S030150 -derived soybean plant by crossing said plant with a second soybean plant to produce progeny seed. However, it remains unclear if the claim is drawn only to the production of progeny that is an F1 hybrid seed, or if it may encompass additional generations of progeny that are derived from these two parents. Claim 12 is also indefinite in the recitation of "crossing soybean variety", since a plant can be crossed, not a variety.

Claims 16 and 17 are indefinite and confusing in that they appear to be duplicates of claims 14 and 15.

Claims 18 and 21 are indefinite in that "herbicide resistance, insect resistance and disease resistance" are not transgenes. However, transgenes may confer these traits.

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 9-22 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to soybean plants and methods of producing soybean plants that involve an indeterminate number of generations and parent plants or of introduced transgenes of unknown function and number, wherein it remains unclear what the identity of the plants in each of the steps would be, much less what the resultant product plant would be. Neither the plants required by each of the steps, nor the plants that are produced by the process are defined by genomic structure or by phenotypic characteristics, and therefore, the claimed invention lacks an

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adequate written description. In addition, the claims are drawn to hybrid soybean seeds, plants produced from said seeds and seeds produced from said plants, wherein one of the parents is S030150 and the other parent plant is not specified. The hybrid plants are not defined by genomic structure or by phenotypic characteristics, and it is unclear what characteristics of S030150 would be present in the claimed hybrid seeds and plants. Due to the segregation and recombination of the parent genomes during meiosis, one cannot predict what traits or combinations of traits will be passed on to any given hybrid seed and plant. In fact, *each* hybrid seed derived from a cross between two genetically distinct parent plants will have unique combinations of characteristics. Therefore, the claimed invention lacks an adequate written description.

See *University of California v. Eli Lilly*, 119 F.3d 1567, 43 USPQ 2d 1405 (Fed. Cir. 1997), where it states: “[a] written description of an invention involving a chemical genus, like a description of a chemical species, ‘requires a precise definition, such as by structure, formula, [or] chemical name,’ of the claimed subject matter sufficient to distinguish it from other materials.”

Therefore, given the lack of written description in the specification with regard to the structural and physical characteristics of the claimed compositions, one skilled in the art would not have been in possession of the genus claimed at the time this application was filed.

Claims 1-22 are rejected under 35 USC 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Since the seed claimed is essential to the claimed invention, it must be obtainable by a repeatable method set forth in the specification or otherwise be readily available to the public. If a seed is not so obtainable or available, the requirements of 35 U.S.C. 112 may be satisfied by a

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deposit thereof. The specification does not disclose a repeatable process to obtain the exact same seed in each occurrence and it is not apparent if such a seed is readily available to the public. It is noted that applicants intend to deposit seeds for S030150 at the ATCC, but there is no indication that the seeds have been deposited and there is no indication in the specification as to public availability. If the deposit of these seeds is made under the terms of the Budapest Treaty, then an affidavit or declaration by the applicants, or a statement by an attorney of record over his or her signature and registration number, stating that the seeds will be irrevocably and without restriction or condition released to the public upon the issuance of a patent would satisfy the deposit requirement made herein. A minimum deposit of 2500 seeds is considered sufficient in the ordinary case to assure availability through the period for which a deposit must be maintained.

If the deposit has not been made under the Budapest Treaty, then in order to certify that the deposit, meets the criteria set forth in 37 CFR 1.801-1.809, applicants may provide assurance of compliance by an affidavit or declaration, or by a statement by an attorney of record over his or her signature and registration number showing that

(a) during the pendency of the application, access to the invention will be afforded to the Commissioner upon request;

(b) all restrictions upon availability to the public will be irrevocably removed upon granting of the patent;

(c) the deposit will be maintained in a public depository for a period of 30 years or 5 years after the last request or for the enforceable life of the patent, whichever is longer; (d) the viability of the biological material at the time of deposit will be tested (see 37 CFR 1.807); and

(e) the deposit will be replaced if it should ever become inviable.

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3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 9-22 are rejected under 35 U.S.C. § 102 (b) as anticipated by or, in the alternative, under 35 U.S.C. § 103 as obvious over U.S. Patent 6,259,001.

Applicants have claimed a plant derived from S030150 soybean after at least one cross and using unspecified second parents, and a method of crossing using said plants, including up to seven generations of crosses and including introduction of herbicide, insect or disease resistance. However, it appears that the claimed plants and seeds are the same as the prior art soybean cultivar of U.S. Patent 6,259,001, given that each has the same characteristics, including: Roundup resistance, white flowers, tan pod, and black hilum, for example. Alternatively, if the claimed plants and seeds of S030150 are not identical to the soybean of U.S. Patent 6,259,001, then it appears that the soybean of U.S. Patent 6,259,001 only differs from the claimed plants and seeds due to minor morphological variation, wherein said minor morphological variation would be expected to occur in different progeny of the same cultivar, and wherein said minor

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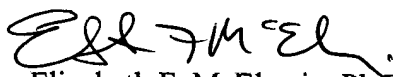
morphological variation would not confer a patentable distinction to S030150. Thus the claimed invention was *prima facie* obvious as a whole to one of ordinary skill in the art at the time it was made, if not anticipated by U.S. Patent 6,259,001 soybean.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth F. McElwain whose telephone number is (571) 272-0802. The examiner can normally be reached on increased flex time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones can be reached on (571) 272-0745. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Elizabeth F. McElwain, Ph.D.
Primary Examiner
Art Unit 1638

EFM